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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/645,576

08/21/2003

Ritu Verma

J6852(C)

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201 7590 04/12/2007  
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EXAMINER

ARNOLD, ERNST V

ART UNIT

PAPER NUMBER

1616

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/12/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/645,576	VERMA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ernst V. Arnold	1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 January 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4-9 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4-9 and 21-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Claims 1, 4-9 and 21-23 are pending. Claims 2, 3 and 10-20 have been cancelled. The Examiner acknowledges Applicant's response filed on 1/22/07. The Examiner has carefully considered Applicant's arguments but does not find them to be persuasive. Applicant's amendment has necessitated a new ground of rejection. This action is FINAL.

Comment: Applicant requested a translation of the relevant parts of Nishihama (WO 02/24153). Until the translation is completed the Examiner is relying on the US equivalent and when the translation is available the Examiner will send Applicant a copy.

#### **Withdrawn rejections:**

Claim 1 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite because of insufficient antecedent basis for this limitation in the claim. Upon further consideration, the Examiner is withdrawing the rejection because the fatty acid is derived from the asymmetric particles.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-9 and 21-23 remain/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation

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“solid asymmetric particles”. It is unclear to the Examiner the metes and bounds of “solid asymmetric particles”. The instant specification discloses that “The solid asymmetric particles may be particles of a fatty acid containing from 12 to 22 carbon atoms...” (page 5, lines 10-11). The Examiner suggests “solid asymmetric fatty acid particles”. Claims 4-9 and 21-23 are indefinite because they are dependent on an indefinite base claim.

**Response to arguments:**

Applicant asserts that the solid asymmetric particles are definite because they may be particles of a fatty acid. The Examiner cannot agree. “May” is permissive language and not definite.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4-9 and 21-23 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Mitchnick et al. (U.S. 5,441,726) in view of Galley et al. (U.S. 5,609,852) and Halls (U.S. 6,267,949).

Applicant claims a process for incorporating ZnO particles in a cosmetic composition comprised of solid asymmetric particles, comprising:

- Melting said solid asymmetric particles to form melted fatty acid;
- Adding un-coated ZnO particles to the melted fatty acid to form a mixture of ZnO and fatty acid;
- Heating said mixture to a temperature of less than about 80°C for about 5 to about 10 minutes;
- Cooling said to a temperature of about 50°C, thereby quenching any reaction between said ZnO and said fatty acid.

**Determination of the scope and content of the prior art**  
**(MPEP 2141.01)**

Mitchnick et al. disclose a creamy foundation composition of the following components:

Composition		
(1) stearic acid	5 wt. %	
(2) lipophilic glycerol monostearate	2.5	10
(3) octostearyl alcohol	1	
(4) propylene glycol monolaurate	3	
(5) squalane	7	
(6) olive oil	8	
(7) purified water	the balance	
(8) antiseptic	a suitable amount	15
(9) triethanolamine	1.2	
(10) sorbitol	3	
(11) titanium oxide	10	
(12) talc	3	
(13) coloring pigment	a suitable amount	
(14) zinc oxide rods	8	20
(15) perfume	a minute amount	

The foundation was prepared by mixing components 11 to 14. The un-coated zinc oxide rods (8% by weight) can be 100 nm in diameter (Column 13, lines 20 and 26-27).

Components 7 through 10 are mixed together to form a solution (Column 13, lines 7-28). The zinc oxide containing component is dispersed in the solution of components 7-10 and heated to 75 °C. Components 1 through 6 (containing 5 % by weight stearic acid) are mixed and heated to 80 °C to form a solution which is then added to the solution containing zinc oxide to produce an emulsion (Column 13, lines 30-33). The emulsion is cooled under stirring to 50 °C and the final perfume ingredient is added (Column 13, lines 33-35). The mixture is cooled under stirring. The Applicant has defined asymmetric particles as fatty acids of 12 to 22 carbon atoms with stearic acid being a preferred asymmetric particle (Specification, pages 8 and 9). The cosmetic preparation of Mitchnick et al. is comprised of 5 % by weight stearic acid and 8 % by weight of zinc oxide. Mixing of these components at a temperature less than about 80 °C and cooled under stirring to a temperature of 50 °C to quench the reaction between ZnO and stearic acid would produce the solid asymmetric particles of the instant invention in at least 10% by weight of the composition (instant claim 7). In instant claim 8, the Examiner interprets about 60 °C to about 70 °C to encompass  $60 \pm 6$  °C to  $70 \pm 7$  °C in which case the temperature of Mitchnick et al., 75 °C, is encompassed by that range.

Galley et al. provide a general teaching for the preparation of sunscreen compositions comprised of metal oxides such as zinc oxide. Galley et al. disclose that

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the oil phase components are heated together to 70-75 °C and then mixed with the aqueous phase containing the metal oxide for 5-10 minutes. The emulsion is then cooled (See: Example 18 Column 9, lines 45-52; Example 19 Column 10, lines 20-26 and Example 20 Column 10, lines 61-67). Galley et al. disclose that fatty acid soaps, such as potassium stearate, are effective emulsifying agents that can be added to the composition (Column 4, line 52).

Halls discloses sunscreen compositions comprised of nano-size ZnO particles in the preferred range of 0.5-15% by weight (Column 4, lines 52-55). Halls provides compositions with 0.5, 1.0, 2.0 and 4.0% by weight zinc oxide in example numbers 8-11, respectively (Column 7, lines 1-8).

### **Ascertainment of the difference between the prior art and the claims**

#### **(MPEP 2141.02)**

1. Mitchnick et al. do not expressly teach heating the mixture of ZnO particles and stearic acid to a temperature of less than about 80 °C for about 5 to about 10 minutes.

2. Mitchnick et al. does not expressly disclose the addition of ZnO in an amount of about 1% to about 4% by weight of the cosmetic composition.

### **Finding of prima facie obviousness**

#### **Rational and Motivation (MPEP 2142-2143)**



1. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a composition containing zinc oxide and stearic acid by the procedure of Mitchnick et al. using the suggested heating period of 5 to 10 minutes of Galley et al. to produce metallic soap coated ZnO particles of the instantly claimed invention.

One of ordinary skill in the art would have been motivated to do this because once the emulsion is formed one of ordinary skill in the art would end the reaction and this is supported by the teachings of Galley et al.

2. It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a composition of Mitchnick et al., using the heating period suggested by Galley et al., containing zinc oxide in the percent weight range of about 1 % to about 4 % as suggested by Halls to produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Halls discloses that the sun protection factor can be adjusted by judicious selection of the amount of ZnO added (0.5 to 4.0 % by weight in this example) thus creating lotions for a wide variety of consumers seeking various levels of sun protection (See: Column 7, lines 1-8).

The Examiner notes for Applicant's benefit that claim 1 does not recite: 1) the amount of fatty acid and zinc oxide; 2) the size of zinc oxide; and 3) the structure of the fatty acid. These limitations are taught in the specification on page 12, lines 5-19 and page 27, lines 5-24. It is the Examiner's position that inclusion of these limitations into claim 1 would help distinguish the instant invention over the prior art.



In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

**Response to arguments:**

Applicant asserts that there is no teaching on the time required to heat the mixture having fatty acid and zinc oxide in the '726 reference. Applicant asserts that no controlled contact will occur between the zinc oxide and fatty acid. The Examiner must respectfully disagree. The only difference between the instant invention and the prior art reference of Mitchnick et al. is the disclosure of the time of reaction when heated at a temperature of less than about 80 C. Mitchnick et al. teach forming an emulsion and Galley provides a time for the reaction to form an emulsion even if such a time was not immediately obvious to one of ordinary skill in the art. Instant claim 1 only requires that the zinc oxide and fatty acid are mixed. Applicant asserts that the cited art teaches pulverized zinc oxide rods and not zinc oxide nano-particles. This is irrelevant as instant claim 1 is drawn to simply ZnO particles. Instant claim 1 only requires that ZnO particles be added to melted fatty acid to form a mixture. The art teaches this. The Examiner cannot be any more clear.

**Claim Rejections - 35 USC § 103**

Claim 1, 6, 8, and 21-23 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishihama (WO 02/24153). Please note that the Examiner is relying on the US equivalent (US 6,949,248) of WO 02/24153 for translation of WO 02/24153.

**Determination of the scope and content of the prior art****(MPEP 2141.01)**

Nishihama teaches a process to prepare a oil in water emulsified sunscreen with the following components:

**TABLE 4**

Example 6 O/W emulsified sunscreen		
1.	Powder of Example 2	12
2.	Zinc white	5
3.	Stearic acid	2
4.	Cetyl alcohol	1
5.	Petroleum	5
6.	Silicone oil	2
7.	Liquid petroleum	10
8.	Glyceryl monostearate (self-emulsifying type)	1
9.	Polyoxyethylene (25 mol) mono oleate	1
10.	Polyethyleneglycol 1500	5
11.	Beegum	0.5
12.	Purified water	55.5
13.	Perfume	suitable amount
14.	Antiseptic	suitable amount

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The process (detailed in column 8, line 56 bridging column 9, line 3) involves adding components 10-12 with stirring at a temperature of 70 C to create a water phase. Components 3-9 were mixed with components 13 and 14 and heated to 70 C to create the oil phase. Note that this contains the fatty acid stearic acid. To the water phase was added powders of components 1 and 2 and dispersed with a homomixer. Zinc white is added at 5%, which the Examiner interprets to read on about 4% of instant claim 23. To the dispersion was added the oil phase, thus bringing zinc oxide into contact with stearic acid, and emulsified with a homomixer and after emulsification, the emulsion was cooled to 35 C with stirring.

**Ascertainment of the difference between the prior art and the claims  
(MPEP 2141.02)**

Nishihama does not expressly teach a heating time for the mixture for about 5 to about 10 minutes.

**Finding of prima facie obviousness  
Rational and Motivation (MPEP 2142-2143)**

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to heat the mixture of Nishihama for about 5 to about 10 minutes and produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Nishihama teaches that once emulsification is complete the mixture is then cooled. In

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the absence of evidence to the contrary, it is the Examiner's position that one of ordinary skill in the art can determine when the emulsification process is finished and such a time would fall in the range of about 5 to about 10 minutes.

In the absence of any criticality/unexpected results, the presently claimed invention is considered *prima facie* obvious over the prior art for the reasons of record and those stated above.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

**Response to arguments:**

Applicant asserts that it is unclear what if any zinc white and stearic acid contact there will be and that the cited art provides no teaching that even remotely suggests the addition of zinc oxide particles to melted fatty acid. The Examiner, respectfully, cannot

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agree. Instant claim 1 only requires mixing the components. Naishihama clearly teaches making an emulsion from the zinc white and oil component containing the stearic acid.

Applicant arguments are not persuasive and Applicant has not provided any data supporting any of Applicant's arguments. Applicant has not amended the claims to be free of the prior art of record. Therefore, the Examiner must maintain the rejections for the reasons of record and those stated above.

### ***Conclusion***

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

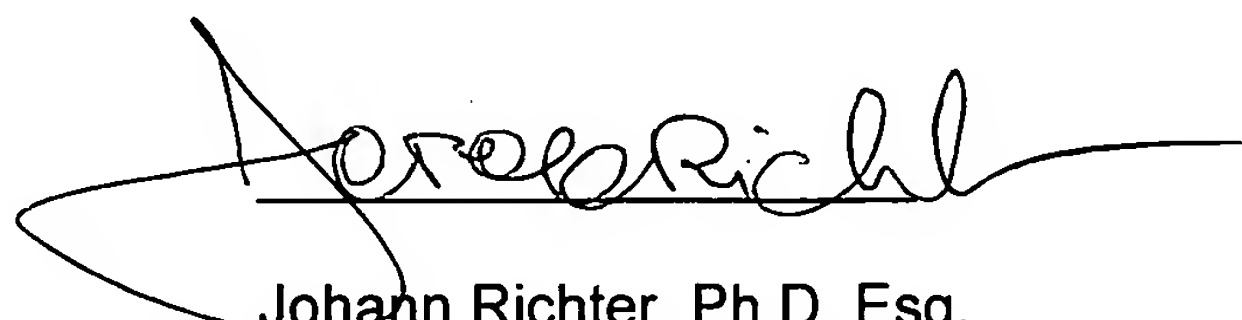
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold  
Patent Examiner  
Technology Center 1600  
Art Unit 1616

A handwritten signature in black ink, appearing to read "Johann Richter", with a large, sweeping flourish extending from the end of the signature.

Johann Richter, Ph.D. Esq.  
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